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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,850	04/09/2004	Michael John Dunkley	0198.00	2666

21968 7590 12/13/2007

NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
ALI, SHUMAYA B	
ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,850	DUNKLEY ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-18,24,28 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-18,24,28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

In response to the office action mailed on 8/22/07, Applicant has amended claims 1,11,12,14,24,28, and 30, and cancelled claims 10,19-23,25-27,29, and 31. Currently, claims 1-9, 11-18, 24, 28, and 30 are pending in the instant application.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 14 recite the limitation "the receptacle" in line 12. There is insufficient antecedent basis for this limitation in the claim. Claims 8-9, 11-13, and 15-18 are rejected for being depending from claims 1 and/or 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9, 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haber et al. US 5,287,850.

As to claim 1, Haber in his specification and drawings (figures 1-3E) discloses a handheld aerosolization apparatus (2) comprising a housing (10) defining a chamber (4 and 6) having a plurality of air inlets (52,40, air inlet though chamber 26 where 18 sits, herby a "third inlet"; and air inlet though mouthpiece assembly 122 or air inlet covered by 124, hereby a "fourth opening"); the chamber being sized to receive a capsule (133) which contains an aerosolizable pharmaceutical formulation (col.1, lines 62-65); a puncturing mechanism (108) in the housing for creating one or more openings in the capsule (see col.5, lines 23-26); a shield (18/8/124) which covers at least one but not all the air inlets (when 18 is closed, as shown in figure 3A closes inlet 52, however, inlet 40 remains open; when 8 is closed, it covers the fourth opening, but not 40; 126 covers the fourth opening but not 40), whereby the shield prevents blockage of the at least one air inlet by a user grasping the apparatus (with respect to shield being 18: the third opening would be prevented from being blocked by the user; with respect to shield being 8 or 124: the fourth opening would be prevented from being blocked by user's hand), and an end section (12) associated with the housing, the end section sized and shaped to be received in a user's mouth (as shown in figure 3E) or nose so that the user may inhale though the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the capsule (see col.5, lines 23-61). Note, "the receptacle" in line 12 hereby read as --the capsule--.

As to claims 2 and 15, Haber discloses the shield is a portion of the end section (see fig.1).

As to claims 3 and 16, Haber discloses the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber (12 has to be removed/engaged to replace capsule, see col.5, lines 23-26, thus 12 is considered removably connected to the housing).

As to claims 4 and 17, Haber discloses the shield is a portion of the end section (124 is a portion of the end section as shown in figure 3B).

As to claim 9, Haber discloses the shield extends longitudinally along the apparatus (see 8 in fig.1).

As to claim 11, Haber discloses the puncture member is adapted to puncture only one end of the capsule (as seen in figure 3B).

As to claim 12, Haber discloses the chamber is elongated and the capsule is received lengthwise within the elongated chamber (see chamber 4 and capsule 133 in figure 3B).

As to claims 13 and 18, Haber discloses wherein the inlet is shaped to create a swirling airflow within the chamber (swirling effect is inherent when user inhales through the inhaler and drawing air though inlet 40, see also col.5, lines 23-61).

As to claim 14, Haber in his specification and drawings (figures 1-3E) discloses a handheld aerosolization apparatus as applied to claim 1.Harber also discloses a shield (18/8/124) which covers a portion but not all the air inlets (when 18 is closed, as shown in figure 3A closes inlet 52, however, inlet 40 remains open; when 8 is closed, it covers the fourth opening, but not 40; 126 covers the fourth opening but not 40. Thus leaving at least one other inlet open, the shield of Haber covers a portion but not all the air inlets as claimed).

Claims 24, 28, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et al. US 4,995,385.

As to claim 24, Valentini in his specification and figures (1-6) discloses an inhalation apparatus comprising a capsule (18) containing an aerosolizable pharmaceutical formulation in a chamber (42) having a plurality of air inlets (figure 1 shows two slits/inlets 32, hereby first and second air inlets), a piercing device (16) that punctures the capsule within the chamber (see col.3, lines 30-35), Valentini further teaches fins (34) on the capsule prevent the fingers inadvertently closing part of the inlets on using the inhaler, so reducing the air flow entering though said inlets (see col.3, lines 60-68). Valentini further teaches the arrangement of fins as shown in figures 1 enables the air to enter though all the inlets even when the fingers rest in position corresponding with said inlet (see col.3, lines 60-68). It is inherent, depending on how the user grabs the inhaler, he/she can shield at least one but not all of the air inlets. For example, if the user grabs the inhaler such that his thumb presses against the first air inlet between fins and rests his other fingers over the fins, then he will block the first air inlet, thus, the first air inlet would be considered blocked by the user's thumb, while the second air inlet would be shield by his other fingers, however, not blocked due to fin structures. Valentini further discloses user of the device inhales though the inhaler to aerosolize pharmaceutical formulation for administering the aerosolized pharmaceutical formulation to the respiratory tract of the user (see col.5, lines 1-50). Thus, the method steps as claimed are inherent result of using the apparatus of Valentini.

As to claims 28 and 30, Valentini in his specification and figures (1-6) discloses an inhalation apparatus comprising a capsule (18) containing an aerosolizable pharmaceutical formulation inserted a chamber (42) having a one or more air inlets (figure 1 shows two

slits/inlets 32, herby first and second air inlets), a piercing device (16) that punctures the capsule within the chamber (see col.3, lines 30-35), Valentini further teaches fins (34) on the capsule prevent the fingers inadvertently closing part of the inlets on using the inhaler, so reducing the air flow entering though said inlets (see col.3, lines 60-68). Valentini further teaches the arrangement of fins as shown in figures 1 enables the air to enter though all the inlets even when the fingers rest in positions corresponding with said inlet (see col.3, lines 60-68). It is inherent, depending on how the user grabs the inhaler; he/she can shield a portion of at least one of the air inlets from being blocked by grasping the chamber. For example, if the user grabs the inhaler such that his thumb presses against a portion of the first air inlet between fins and rests his other fingers over the fins, then his thumb will block a portion of the first inlet while the second inlet would be covered by the other finger. This grabbing position however would not block the second inlet because of the fins, thereby would only shield the second inlet. Valentini further discloses the user inhales though the inhaler following piercing the capsule aerosolizes the pharmaceutical formulation which is administered to the user respiratory tract (see col.5, lines 1-50). Thus, the method steps as claimed are inherent result of using the apparatus of Valentini.

Allowable Subject Matter

Claims 5-8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 11-18, 24, 28, and 30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. James (4,116,195), Ohki et al. (5,715,811), Lerk et al. (5,301,666), and Newhouse (5,201,308) pertain to powder inhaler.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/10/07

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
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12/10/07